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|-----------------|-------------|----------------------|---------------------|------------------|
| 09/116,502 | 07/16/1998 | ROBERT D. FALLON | CL-1035 | 2625 |

23906 7590 10/03/2003

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 10/03/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/116,502

Applicant(s)

FALLON ET AL.

Examiner

Christian L Fronda

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-23 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 and 22 is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8-17, 19-21, 23 and 25-27 is/are rejected.
- 7) ☒ Claim(s) 2 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 1998 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

1. In the **SUPPLEMENTAL AMENDMENT** dated October 8, 2001, Applicants have deleted claim 15 and amended claims 1, 6, 8, 9, 14, 16-19, 25, and 26.
2. Claims 1-14, 16-23, and 25-27 are under consideration in this Office Action.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1, 3-6, 8-14, 16-17, 19-21, 23, and 25-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 3-6 are directed to any method for the bioproduction of C6 to C22 mono- or di-carboxylic acid using any transformed *Pichia pastoris* having any foreign gene encoding any cytochrome P450 monooxygenase of any amino acid sequence and structure and optionally any foreign gene encoding any cytochrome P450 reductase of any amino acid sequence and structure.

The specification only provides a written description of the transformed *Pichia pastoris* strain used in the recited method as ATCC 74409. There is no written description for [any transformed *Pichia pastoris* having any foreign gene encoding any cytochrome P450 monooxygenase of any amino acid sequence and structure and optionally any foreign gene encoding any cytochrome P450 reductase of any amino acid sequence and structure.]

Claims 8-14 are directed to any method for the bioproduction of C6 to C22 mono- or di-carboxylic acid using any transformed *Candida maltosa* comprising any gene encoding any cytochrome P450 monooxygenase of any amino acid sequence and structure, any gene encoding any cytochrome P450 reductase of any amino acid sequence and structure, or both of said P450 monooxygenase and cytochrome P450 reductase. The specification only provides a written description of the transformed *Candida maltosa* strain used in the recited method as ATCC

Art Unit: 1652

74431. There is no written description for any transformed *Candida maltosa* comprising any gene encoding any cytochrome P450 monooxygenase of any amino acid sequence and structure, any gene encoding any cytochrome P450 reductase of any amino acid sequence and structure, or both of said P450 monooxygenase and cytochrome P450 reductase.

Claims 16-17, 19-21, and 23 are directed to any transformed *Candida maltosa* having a disruption of any POX4 genes of any nucleotide sequence whereby beta-oxidation pathway is functionally blocked and use of said transformed *Candida maltosa* in any method for the bioproduction of C6 to C22 mono- or di-carboxylic acid. The specification only provides a written description of the transformed *Candida maltosa* strain used in the recited method as ATCC 74430. There is no written description for any transformed *Candida maltosa* having a disruption of any POX4 genes of any nucleotide sequence whereby beta-oxidation pathway is functionally blocked and use of said transformed *Candida maltosa* in any method for the bioproduction of C6 to C22 mono- or di-carboxylic acid.

Claims 25-27 are directed to any isolated DNA fragment comprising any gene of any nucleotide sequence encoding any cytochrome P450 monooxygenase and any gene of any nucleotide sequence encoding any cytochrome P450 reductase. The specification only provides a written description for plasmids pSW84 and pSW87.28. There is no written description for any DNA fragment composing any gene of any nucleotide sequence encoding any cytochrome P450 monooxygenase and any gene of any nucleotide sequence encoding any cytochrome P450 reductase.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Conclusion

5. Claims 18 and 22 are allowed.

6. Claims 2 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is

Application/Control Number: 09/116,502

Page 4

Art Unit: 1652

(703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600